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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/630,345	07/31/2000	Anand C. Burman	U 012858-1	5580

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EXAMINER
MOHAMED, ABDEL A

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 08/19/2003 16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/630,345	BURMAN ET AL.	
	Examiner	Art Unit	
	Abdel A. Mohamed	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 July 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9 and 14-27* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9 and 14-27* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

ACKNOWLEDGMENT OF REMARKS AND STATUS OF THE CLAIMS

1. The remarks filed 7/17/03 is acknowledged, entered and considered. As noted correctly by Applicant US Patent application 09/248,381 issued as US Patent 6,492,330. Thus, the application that was meant by the Examiner is US Patent application 09/248,382. Further, the Examiner inadvertently rejected claims 1-27 while Applicant canceled claims 10-13 on amendment A filed 10/28/02 (Paper No. 11). Hence, claims 1-9 and 14-27 were pending in the application and the rejections should have been directed to such claims. Any inconvenience caused by such mistakes is regretted. Thus, claims 1-9 and 14-27 are now pending in the application. The rejection under the judicially created doctrine of double patenting and the provisional rejections under the judicially created doctrine of obviousness-type double patenting are maintained for the reasons of record as reiterated below:

HEADINGS FOR NONSTATUTORY DOUBLE PATENTING

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

DOUBLE PATENTING-NONSTATUTORY WITH A PATENT

3. Claims 1-9 and 14-27 are rejected under the under the judicially created doctrine of double patenting over claims 1-33 of U.S. Patent No. 6,492,330.

The subject matter claimed in the instant application is set forth in the '330 patent claims. The patent and the application claim common subject matter, as follows: The instantly claimed invention and the patent claim the use of peptides individually or in combination for the treatment of cancer. The only difference between the '330 patent claims and the claims of the instant application is the scope of the claims in which the instantly claimed invention is limited to peptidic sequences of SEQ ID NOS:1-7, wherein "X" recited in sequence of claim 1 is replaced by alkanoyl groups while the '330 patent claims is broadly directed to peptidic sequences of SEQ ID NOS:1-25 and the peptides are further used for treating angiogenesis. Both inventions are basically the same since they are made by the same procedure for the same purpose. Nevertheless, the only difference between the two inventions is the scope of the claims in which the invention of the instantly claimed invention appears to be specific in scope than that of the '330

patent which is broader because the patent's claims encompasses the use of peptidic sequences of SEQ ID NOS:1-25 for treatment of cancer and/or angiogenesis while the instantly claimed invention claims only the use of peptidic sequences of SEQ ID NOS:1-7 for treatment of cancer. Further, the instantly claimed invention is more specific in that the sequence recited in claim 1 could be replaced by any of alkanoyl groups recited in claim 2. However, one skilled in the art would easily replace any of the alkanoyl groups recited in claim 2 for the intended purpose of protecting the peptide of interest. Thus, since both inventions are directed to peptides isolated from the same source for the same purposes; it would have been an obvious variation to use or adapt either the broader scope or the specific procedures for the same purposes. Therefore, both inventions are an obvious variation of the other since the same peptides are used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other.

PROVISIONAL REJECTION OF OBVIOUSNESS-TYPE DOUBLE PATENTING

4. Claims 1-9 and 14-27 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4 and 32-36 of copending Application No. 09/248,381. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instantly claimed invention (Serial No. 09/630,345) is directed to use of peptides individually or in combination for the treatment of cancer having peptidic SEQ ID NOS:1-7. Similarly, Serial No. 09/~~630,345~~ 248,382 is directed to the use of peptides individually or in combination for

the treatment of cancer having peptidic sequences of SEQ ID NOS:1-9, wherein at least one of the amino acids at position 1-8 is replaced by Deg in SEQ ID NO:1. Both inventions are basically the same since they are made by the same procedure for the same purpose. Nevertheless, the only difference between the two inventions is the replacement of the sequences and the numbers of sequences disclosed. In the instant application SEQ ID NOS:1-7 have been disclosed while in copending application the peptidic sequences disclosed are SEQ ID NOS:1-9. With respect to the replacement of sequences, the sequence recited in claim 1 of the instant application the "X" could be replaced by the alkanoyl groups while SEQ ID NO:1 in claim 1 of the copending application could be replaced by Deg at least in one of the amino acid position 1-8. However, one skilled in the art would easily replace any of the alkanoyl groups recited in claim 2 of the instant application for the purpose of protecting the peptide thereof or by the SEQ ID NO:1 in claim 1 of copending application at least one of the amino acid positions 1-8 of SEQ ID NO:1 by Deg (- -diethyl glycine) for the intended purpose of making the peptide more stable and resistant to enzymatic degradation. Thus, since both inventions are directed to peptides isolated from the same source for the same purposes; it would have been an obvious variation to use or adapt either the alkanoyl groups or the Deg replacement because both procedures use the same peptides for the same purposes. Therefore, both inventions are an obvious variation of the other since the same peptides are used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

ARGUMENTS ARE NOT PERSUASIVE

DOUBLE PATENTING-NONSTATUTORY WITH A PATENT

5. The rejection of claims 1-9 and 14-27 under the judicially created doctrine of double patenting over claims 1-33 of U.S. Patent No. 6,492,330.

Applicant's arguments filed 7/17/03 have been fully considered but they are not persuasive. Applicant has argued that claim 1 of this application defines a peptide X-Leu-Met-Tyr-Pro-Thr-Leu-Lys-Y wherein X is aceteyl or straight, branched or cyclic alkanoyl group from 3-16 carbon atoms and Y is carboxyl terminal residue selected from OH or amino; or a pharmaceutically acceptable salt of the peptide. None of the peptides defined in the claims of this application are obvious in view of the peptides claimed in US Patent 6,492,330. None of the peptides claimed in US Patent 6,492,330 include a group X where X is acetyl or straight, branched, or cyclic alkanoyl group from 3-16 carbon atoms is unpersuasive. Contrary to Applicant's arguments, the instantly claimed invention and the patent claim the use of peptides individually or in combination for the treatment of cancer. The only difference between the '330 patent claims and the claims of the instant application is the scope of the claims in which the instantly claimed invention is limited to peptidic sequences of SEQ ID NOS:1-7, wherein "X" recited in sequence of claim 1 is replaced by alkanoyl groups while the '330 patent claims is broadly directed to peptidic sequences of SEQ ID NOS:1-25 and the peptides are further used for treating angiogenesis. Further, SEQ ID NO:13 of claim 1 in the patent

is the same as SEQ ID NO:7 of claim 1 of the instantly claimed invention, and also in both situations, the Y is carboxyl terminal residue, which is OH. Although, the instantly claimed invention is more specific in that the sequence recited in claim 1 could be replaced by any of alkanoyl groups recited in claim 2. However, it is an obvious variation to replace any of the alkanoyl groups recited in claim 2 for the intended purpose of protecting the peptide of interest.

Therefore, both inventions are basically the same since they are made by the same procedure for the same purpose. Thus, since both inventions are directed to peptides isolated from the same source for the same purposes; it is an obvious variation to use or adapt either the broader scope or the specific because both procedures use the same peptides for the same purposes. Accordingly, both inventions are an obvious variation of the other since the same peptides are used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other. Thus, absent of showing of a difference in the claim(s), it is apparent that the polypeptide and use thereof in US Patent No. 6,492,330 claims are an obvious variation of the current claims.

PROVISIONAL REJECTION OF OBVIOUSNESS-TYPE DOUBLE PATENTING

6. The provisional rejection of claims 1-9 and 14-27 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4 and 32-36 of copending Application No. 09/248,382. Applicant has argued that there is

no legal or factual basis for the statement that both inventions are basically the same since they are made by the same procedure for the same purpose because it could mean that once one patent has been granted for a compound that can be prepared by a standard chemical reaction such as a Diels-Alder reaction and can be used to treat, for example, lung cancer and no other patent could be granted for another compound that can be prepared using a Diels-Adler reaction and that can be used for treating lung cancer because there is already one patent for the same purpose. Further, with respect to the statement that "both inventions are an obvious variation of the other since the same peptides are used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other." Applicant has argued that (A) the claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus, the obviousness of making the combination; (C) the references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention and (D) reasonable expectation of success is the standard with which obviousness is determined. Furthermore, the claims of US patent application 09/248,382 do not suggest a peptide of the sequence ID NO:7 of the instant claim 1 a group of X where X is acetyl or straight, branched, or cyclic alkanoyl group from 3 to 16 carbon atoms is unpersuasive.

Contrary to Applicant's arguments, the claims of copending application Serial No. 09/248,382 is directed to the use of peptides individually or in combination for the treatment of cancer having peptidic sequences of SEQ ID NOS:1-9, wherein at least

one of the amino acids at position 1-8 is replaced by Deg in SEQ ID NO:1; while the instantly claimed invention (Serial No. 09/630,345) is directed to use of peptides individually or in combination for the treatment of cancer having peptidic SEQ ID NOS:1-7. Thus, both inventions are using the same polypeptide (i.e. SEQ ID NOS:1-9 and SEQ ID NOS:1-7, respectively) for the same purpose (i.e., to treat cancers such as breast, lung, prostate, etc.,). With respect to the replacement of an amino acid by Deg, the Examiner has shown on copending application Serial No. 09/248,382 that on page 5 of Paper NO. 17 that it is conventional and known in the art to modify the peptides as claimed in copending application (i.e., substitution of D amino acid for L amino acid in a peptide sequence) for treating cancer. Thus, in view of what is known in the art as discussed in Paper No. 17 of copending application, it is an obvious variation to replace SEQ ID NO:1 in claim 1 of the copending application by Deg at least in one of the amino acid position 1-8 while the sequence recited in claim 1 of instant application the "X" could be replaced the alkanoyl groups. Hence, at least one of the amino acid positions 1-8 of SEQ ID NO:1 by Deg (τ -diethyl glycine) would have been replaced for the intended purpose of making the peptide more stable and resistant to enzymatic degradation or by any of the alkanoyl groups recited in claim 2 of the instant application for the purpose of protecting the peptide thereof. Thus, since both inventions are directed to peptides isolated from the same source for the same purposes; it would have been an obvious variation to use or adapt either the Deg or the alkanoyl group's replacement.

Therefore, both inventions are an obvious variation of the other since the same peptides are used for the same purpose, and as such, one of ordinary skill in the art would envision both sets of claims as one invention and obvious variation of each other. Thus, absent of showing of a difference in the claim(s), it is apparent that the polypeptide and use thereof in copending application Serial No. 09/248,382 claims are an obvious variation of the current claims.

7. **ACTION IS FINAL**

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. **CONCLUSIONS AND FUTURE CORRESPONDANCE**

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Abdel A. Mohamed whose telephone number is (703) 308-3966. The examiner can normally be reached on Monday through Friday from 7:30 a.m. to 5:00 p.m. The examiner can also be reached on alternate Fridays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S.F. Low can be reached on (703) 308-2923. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

AAM/Mohamed/AAM
August 14, 2003

Christopher S. F. Low

CHRISTOPHER S. F. LOW
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